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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/556,102	04/21/2000	Christopher T. Davey	BSC-134	6730

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EXAMINER

DESANTO, MATTHEW F

ART UNIT PAPER NUMBER

3763

DATE MAILED: 08/01/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/556,102

Applicant(s)

DAVEY, CHRISTOPHER T.

Examiner

Matthew F DeSanto

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 07 June 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-45 is/are pending in the application.
- 4a) Of the above claim(s) 1-10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11-45 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4 and 5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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## DETAILED ACTION

### *Election/Restrictions*

1. Applicant's election with traverse of claims 1-10 in Paper No. 7 is acknowledged. Since no argument is given, the restriction requirement is still deemed proper and is therefore made **FINAL**.
2. Claims 1-10 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 7.

### *Claim Rejections - 35 USC § 102*

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined

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under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

4. Claims 11, 17, 18, 22, 24, 34, 35, 45 are rejected under 35 U.S.C. 102(b) as being anticipated by Hermann et al. (USPN 5599305). Hermann et al. discloses a proximal hub portion (36), an elongated body portion extending distally from the proximal hub portion (16, 18, 40), and a passageway extending through the proximal hub and elongated body portion, being defined by an inner surface of the sheath, and a valve (38) having a foam material filling at least some of the length of the passageway, the length of the foam material within the passageway being greater than the width of the foam material at any point within the passageway, (Fig. 3, Col 9, line 58 – Col 10, line 16) and one or more self-sealing slits in the foam material, where none of the slits extend in width to the inner surface of the sheath, and where the foam material is affixed to a portion of an inner surface of the sheath that defines the passageway, (Col. 9, line 41 – Col. 10, line 23).

As in claim 17, 18, wherein the elongated body portion comprises at least a first section, and a second section, where the first cross-sectional area is larger than the second cross-sectional area and further comprises a shoulder disposed within the passageway and between the first and second sections. The reference shows a first cross-sectional area starting after the valve (38), and then the shoulder (40), and then the second cross-sectional area (24). (Figure 2, and 3).

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As in claim 22, 34, 45 wherein the foam material comprises a closed cell foam.  
(Col 7, lines 19-58).

As to claim 35, "an injected foam material" is a product by process, because this claims refers to an apparatus, not a method of making. Therefore, the apparatus needs to only have a foam material, since "injected" is not given much patentable weight. The term "injected foam material" is interpreted as a placing the foam material in the sheath.

5. Claims 11, 12 – 16, 19 – 21, 23 – 33, 35 – 44 are rejected under 35 U.S.C. 102(e) as being anticipated by Heck (USPN 6083207). Heck discloses a proximal hub portion (12), an elongated body portion extending distally from the proximal hub portion (20), and a passageway (34,36,208) extending through the proximal hub and elongated body portion, being defined by an inner surface of the sheath, and a valve (14) having a foam material filling at least some of the length of the passageway, the length of the foam material within the passageway being greater than the width of the foam material at any point within the passageway, (Col 5, lines 46-59) and one or more self-sealing slits in the foam material, where none of the slits extend in width to the inner surface of the sheath, and where the foam material is affixed to a portion of an inner surface of the sheath that defines the passageway, (Column 6, lines 1-9).

As to claim 12, 25, 36 where the foam material includes a proximal and distal section, where one or more slits in the distal section remaining sealed as the flexible

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medical device is introduced first into the one or more slits in the proximal section.

(Column 6, lines 36-63).

As to claim 13, 26, 39, wherein the sheath comprises a pair of lines extending some length and on opposite sides of the sheath, and where the sheath is separable.

(Figure 3).

As to claim 14, 27, 40, where the lines comprise scorings. (Figure 3).

As to claim 15, 28, 41, wherein the valve is separable with the sheath. (Figure 3).

As to claim 16, 29, wherein the valve is splittable into two halves along one of the self-sealing slits. (Figure 3).

As to claims 19,20, 31, 32, 42, 43, where the foam material defines a depression, which comprises a conical shape for receiving the flexible medical device. (Figure 5; 42,38).

As to claim 21, 33, 44 wherein the proximal hub portion comprises a pair of wings. (Figure 1, ref 16).

As to claim 35, "an injected foam material" is a product by process, because this claims refers to an apparatus, not a method of making. Therefore, the apparatus needs to only have a foam material, since "injected" is not given much patentable weight. The term "injected foam material" is interpreted as a placing the foam material in the sheath.

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**Conclusion**


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew F DeSanto whose telephone number is 1-703-305-3292. The examiner can normally be reached on Monday-Friday 8:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 1-703-308-3552. The fax phone numbers for the organization where this application or proceeding is assigned are 1-703-872-9302 for regular communications and 1-703-872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 1-703-308-0858.



Matthew DeSanto  
Art Unit 3763  
July 26, 2002



ANH TUAN T. NGUYEN  
PRIMARY EXAMINER

7/29/02